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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,239	11/10/2000	Robert C Chang	FG0219 US	4907

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/710,239	Applicant(s) CHANG ET AL.	
	Examiner Chih-Min Kam	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5,6,30,43-45,47,48,50,54-57,59,62,64-68,70-73,76-83,90 and 92-94 is/are allowed.
- 6) ☒ Claim(s) 2-4,8,12,21,61,75,89 and 98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 2-6,8,12,21,30,43-45,47,48,50,54-57,59,61,62,64-68,70-73,75-83,89,90,92-94 and 98.

DETAILED ACTION

Status of the claims

1. Claims 2-6, 8, 12, 21, 30, 43-45, 47, 48, 50, 54-57, 59, 61, 62, 64-68, 70-73, 75-83, 89, 90, 92-94 and 98 are pending.

Applicants' amendment filed March 15, 2004 is acknowledged, and applicant's response has been fully considered. Claims 78, 82, 83, 89 and 98 have been amended, and claims 9, 13-15, 42, 49, 51, 58, 60, 84-88, 91 and 95-97 have been cancelled. Therefore, claims 2-6, 8, 12, 21, 30, 43-45, 47, 48, 50, 54-57, 59, 61, 62, 64-68, 70-73, 75-83, 89, 90, 92-94 and 98 are examined.

Objection Withdrawn

2. The previous objection to claim 83 is withdrawn in view of applicant's amendment to the claim in the amendment filed March 15, 2004.

Rejection Withdrawn

Claim Rejections-Obviousness Type Double Patenting

3. The previous rejection of claims 14, 15, 84, 87, 88, 96 and 97 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 29 of U. S. Patent 6,413,742, is withdrawn in view of applicants' cancellation of the claim, and applicants' response at pages 10-11 in the amendment filed March 15, 2004.
4. The previous rejection of claims 14, 15, 84, 87, 88, 96 and 97 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 31 of U. S. Patent 6,428,978, is withdrawn in view of applicants' cancellation of the claim, and applicants' response at page 11 in the amendment filed March 15, 2004.

5. The previous rejection of claims 9, 13, 14, 84, 87, 88 and 95-97 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 12-18 and 47-48 of copending Application No. 10/232,175 (US 2003/0064074), is withdrawn in view of applicants' cancellation of the claim in the amendment filed March 15, 2004.

Claim Rejections - 35 USC § 112

6. The previous rejection of claims 88 and 97 under 35 USC § 112, second paragraph, is withdrawn in view of applicants' cancellation of the claim in the amendment filed March 15, 2004.

Claim Rejections - 35 USC § 102

7. The previous rejection of claims 13-15, 42, 49, 51, 58, 60, 84-87, 91, 95 and 96 under 35 USC § 102(b), as being anticipated by Tardy *et al.* (U. S. Patent 5,618,551, April 8, 1997), is withdrawn in view of applicant's cancellation of the claim, and applicants' response at page 12 in the amendment filed March 15, 2004.

8. The previous rejection of claims 42, 49, 51, 60-62, 84, 87 and 96 under 35 USC § 102(e), as being anticipated by Wironen *et al.* (U S 2002/0098222 A1, filed March 13, 1997), is withdrawn in view of applicant's cancellation of the claim, and applicants' response at page 12 in the amendment filed March 15, 2004.

9. The previous rejection of claims 9, 14, 15, 84, 87, 88, 96 and 97 under 35 USC § 102(e), as being anticipated by Olson *et al.* (U. S. Patent 6,428,978, priority date, May 8, 1998), is withdrawn in view of applicant's cancellation of the claim, and applicants' response at page 13 in the amendment filed March 15, 2004.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 2, 3, 8, 12, 21, 61, 75 and 98 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 12-18 and 47-48 of copending Application No. 10/232,175 (US 2003/0064074). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 2, 3, 8, 12, 21, 61, 75 and 98 in the instant application disclose a recombinant human gelatin, a recombinant gelatin, a composition or a pharmaceutical composition comprising the recombinant human gelatin. This is obvious in view of claims 1-7, 12-18 and 47-48 in the co-pending application which discloses a vaccine composition comprising a recombinant gelatin or a recombinant human gelatin, and a method of producing the vaccine composition. Since both the instant application and the co-pending application are directed to a composition comprising the recombinant gelatin. Therefore, claims 2, 3, 8, 12, 21, 61, 75 and 98 in instant application and claims 1-7, 12-18 and 47-48 of the co-pending application (10/232,175) are obvious variations of a recombinant human gelatin, a composition or a pharmaceutical composition comprising the recombinant human gelatin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In response, applicants indicate this is provisional rejection as each of these applications is yet pending, and no terminal disclaimer needs be filed at the present time. The response has been considered, and the rejection remains.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 3, 89 and 98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
12. Claim 3 is indefinite as to molecular weight range is “about 0 to 50 kDa”, it is not clear how the molecular weight of recombinant human gelatin can be 0 kDa.
13. Claims 89 and 98 are indefinite because of the use of the term “altered collagen construct”. The term “altered collagen construct” renders the claim indefinite, it is not clear what alteration is made in the collagen construct, where is the alteration in the construct, and what is the resulting collagen construct.

In response, applicants indicate the specification states that “an altered collagen construct is a polynucleotide comprising a sequence that is altered through deletions, additions, substitutions, or other changes from a naturally occurring collagen gene”, and altered collagen construct also includes constructs containing a polynucleotide encoding at least one collagenous domain, but not encoding naturally occurring collagen (pages 11-12 of the response). The

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response has been fully considered, however, the argument is not found persuasive because it is not clear what resulting collagen construct is obtained after the alteration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Note that patentability of the product by process resides in the product. Therefore, the product prepared by biochemical purification anticipates the same product produced by recombinant means. In the instant case, the gelatin indicated in the reference is not distinguishable from the recombinant gelatin of the claimed invention.

14. Claims 4, 12 and 90 are rejected under 35 U.S.C. 102(e) as being anticipated by Wunderlich *et al.* (U. S. Patent 6,068,854, priority date December 4, 1992).

Wunderlich *et al.* teach a gelatin matrix is used for controlled active substance release in a peroral depot medicament, and the types of gelatin have a part of the molar fraction above 300 kD of at least 20% (claim 4), and a particularly homogeneous distribution of the microcapsules obtained by use of type A and B gelatins with identical or similar molecular weight distribution (column 8, lines 20-36, Table 1; claims 12 and 90).

Conclusion

15. Claims 2-4, 8, 12, 21, 61, 75, 89 and 98 are rejected, and it appears claims 5-6, 30, 43-45, 47, 48, 50, 54-57, 59, 62, 64-68, 70-73, 76-83, 90 and 92-94 are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.
Patent Examiner

C-M/K

June 3, 2004

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